



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

**Agency Information Collection Activities: Submission to OMB for Review and Approval;
Public Comment Request**

Action: Notice

Summary: In compliance with section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the Health Resources and Services Administration (HRSA) will submit an Information Collection Request (ICR) to the Office of Management and Budget (OMB).

Comments submitted during the first public review of this ICR will be provided to OMB. OMB will accept further comments from the public during the review and approval period. To request a copy of the clearance requests submitted to OMB for review, email paperwork@hrsa.gov or call the HRSA Reports Clearance Office at (301) 443-1984.

**Information Collection Request Title: Drug Pricing Program Reporting Requirements
(OMB No. 0915-0176) – [Extension]**

Abstract: Section 602 of Public Law 102–585, the Veterans Health Care Act of 1992, enacted section 340B of the Public Health Service Act (PHS Act), “Limitation on Prices of Drugs Purchased by Covered Entities.” Section 340B provides that a manufacturer who sells covered outpatient drugs to eligible entities must sign a pharmaceutical pricing agreement with the

Secretary of Health and Human Services in which the manufacturer agrees to charge a price for covered outpatient drugs that will not exceed an amount determined under a statutory formula. Covered entities which choose to participate in the section 340B drug discount program must comply with the requirements of 340B(a)(5) of the PHS Act. Section 340B(a)(5)(A) prohibits a covered entity from accepting a discount for a drug that would also generate a Medicaid rebate. Further, section 340B(a)(5)(B) prohibits a covered entity from reselling or otherwise transferring a discounted drug to a person who is not a patient of the entity.

In response to the statutory mandate of section 340B(a)(5)(C) to develop audit guidelines and because of the potential for disputes involving covered entities and participating drug manufacturers, the HRSA Office of Pharmacy Affairs (OPA) developed a dispute resolution process for manufacturers and covered entities as well as manufacturer guidelines for audit of covered entities.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions, to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information, to train personnel and to be able to respond to a collection of information, to search data sources, to complete and review the collection of information, and to transmit or otherwise disclose the information. The total annual burden hours estimated for this ICR are summarized in the table below.

The annual estimate of burden is as follows:

Reporting/ Notification Requirement	No. of Respondents	Responses per Respondent	Total Responses	Hours/ Response	Total Burden Hours
AUDITS					
Good Faith Resolution ¹	10	1	10	40	400
Audit Notification of Entity ¹	10	1	10	4	40
Audit Workplan ¹	8	1	8	10	80
Audit Report ¹	6	1	6	10	60
Entity Response	6	1	6	8	48
DISPUTE RESOLUTION					
Mediation Request	10	4	40	10	400
Rebuttal	10	1	10	16	160
TOTAL	50		80		1188

¹ Prepared by the manufacturer

Recordkeeping Burden:

Recordkeeping requirement	Number of recordkeepers	Hours of recordkeeping	Total Burden
Dispute Records	50	0.5	25

Addresses: Submit your comments to the desk officer for HRSA, either by email to OIRA_submission@omb.eop.gov or by fax to 202-395-5806. Please direct all correspondence to the “attention of the desk officer for HRSA.”

Deadline: Comments on this ICR should be received within 30 days of this notice.

Dated: February 13, 2013

Bahar Niakan

Director, Division of Policy and Information Coordination

[FR Doc. 2013-03912 Filed 02/20/2013 at 8:45 am; Publication Date: 02/21/2013]